

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL)) MDL No. 16-2740
PRODUCTS LIABILITY)
LITIGATION) SECTION: "H" (5)
)
This document relates to:)
Kelly Gahan, No. 16-15283)

ORDER AND REASONS

Before the Court is a Motion for Summary Judgment (Doc. 5730). The Court held oral argument on the Motion on December 5, 2019. For the following reasons, the Motion is **GRANTED**.

BACKGROUND

Plaintiffs in this multidistrict litigation (“MDL”) are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel,¹ that Plaintiffs were administered for the treatment of breast cancer or other forms of cancer. Plaintiffs allege that the drug caused permanent alopecia—in other words, permanent hair loss. Plaintiffs bring claims of failure to warn, negligent misrepresentation, fraudulent misrepresentation, and more.

Defendants bring this Motion for Summary Judgment requesting that all claims filed by Plaintiff Kelly Gahan be dismissed. Dr. Gahan is an emergency room physician and was diagnosed with breast cancer in 2013. She completed her treatment that same year. Plaintiff Gahan asserts eight claims against Defendants under Colorado law: (I) strict products liability for failure to warn; (II) strict products liability for misrepresentation; (III) negligence;

¹ Docetaxel is the generic version of Taxotere.

(IV) negligent misrepresentation; (V) fraudulent misrepresentation; (VI) fraudulent concealment; (VII) fraud and deceit; and (VIII) breach of express warranty. Counts II and VIII have been dismissed in pre-trial orders, and Plaintiff does not oppose summary judgment on Count IV for negligent misrepresentation.² Accordingly, five of her eight claims are in dispute, and Defendants seek summary judgment on all of them.

LEGAL STANDARD

Summary judgment is warranted where “there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.”³ A genuine issue of fact exists only “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.”⁴ Rule 56 of the Federal Rules of Civil Procedure “mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.”⁵

LAW AND ANALYSIS

Defendants aver that Plaintiff’s failure to warn claims fail because Plaintiff’s physician’s prescribing decision would not have changed even with a different warning. Defendants next argue that Plaintiff’s fraud-based claims

² Plaintiff acknowledges that Colorado law restricts negligent misrepresentation claims to certain contexts. Accordingly, the Court grants summary judgment on this claim.

³ Fed. R. Civ. P. 56.

⁴ *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

⁵ *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

fail because Defendants never made any direct representation to Plaintiff. The Court will address the arguments in turn.

I. Plaintiff's Failure to Warn Claims

Defendants argue that they are entitled to summary judgment on Plaintiff's negligence and strict liability claims for failure to warn. Relying in part on the learned intermediary doctrine, Defendants argue that Plaintiff has failed to introduce evidence that a different warning from Defendants would have led Dr. Gahan's oncologist, Dr. Virginia Borges, to change her prescribing decision. Defendants aver that Dr. Borges had prior independent knowledge of the risk of permanent alopecia associated with Taxotere and nonetheless prescribed a Taxotere regimen to Plaintiff Gahan. Defendants argue that because of Dr. Borges's actions as an intermediary, the causation chain is broken. Notably, Defendants are not asking this Court to find that their warning to Dr. Borges was adequate. Instead, they ask the Court to find that the alleged inadequate warning did not cause Plaintiff's injury.

In response, Plaintiff argues that the learned intermediary doctrine does not absolve Defendants of liability. Plaintiff argues that the application of the learned intermediary doctrine requires a finding that the drug label adequately advised the physician of the risk at issue. Plaintiff avers that in this case, the Taxotere label included no warning of the risk of permanent alopecia. Therefore, according to Plaintiff, the doctrine is inapplicable, even though Dr. Borges had some independent knowledge of the risk and prescribed Taxotere despite this knowledge.

To prevail on a negligence or strict liability claim of failure to warn under Colorado law, a plaintiff must prove causation.⁶ Specifically, a plaintiff must prove that the manufacturer's inadequate warning caused the plaintiff's injury.⁷ According to Defendants, the learned intermediary doctrine bears on the causation analysis. Plaintiff disagrees. The learned intermediary doctrine provides that in cases involving prescription drugs, the manufacturer's duty to warn runs to the prescribing physician, not the ultimate user.⁸ This is because the physician is "trained to assess the risks and benefits of the drug as applied clinically to a particular patient."⁹ Under this doctrine, Colorado law permits the granting of summary judgment in cases where a manufacturer provided an adequate warning to the prescribing physician.¹⁰

Defendants emphasize that no label change would have altered Dr. Borges's recommendation that Gahan use a Taxotere regimen. However, this Court does not view this issue so narrowly. This Court has previously ruled in this MDL that a plaintiff must show that an adequate warning would have changed her doctor's prescribing decision.¹¹ Indeed, Colorado law is consistent with this.¹² Under this framework focusing on the prescribing decision, the Court finds that Plaintiff has failed to create an issue of fact on causation.

As this Court has noted, the chemotherapy context is unique.¹³ A doctor will only prescribe and administer a certain chemotherapy regimen when she

⁶ O'Connell v. Biomet, Inc., 250 P.3d 1278, 1280–81 (Colo. App. 2010) (strict liability claim).

⁷ See *id.* at 1281.

⁸ See *id.*

⁹ *Id.*

¹⁰ See Caveny v. CIBA-GEIGY Corp., 818 F. Supp. 1404, 1404–06 (D. Colo. 1992) (granting summary judgment where package insert warned prescribing physician of possible adverse reaction with probable causal relationship).

¹¹ Doc. 7571 (applying Georgia and Louisiana law).

¹² See O'Connell, 250 P.3d at 1281 ("The plaintiff has the burden of proving that the manufacturer gave an inadequate warning that caused the injury.").

¹³ Doc. 7571.

has informed consent from her patient. If the patient refuses to give informed consent to a certain recommended regimen, the doctor must adapt her prescribing decision or lose her patient to another doctor.

Here, the uncontested evidence shows that Dr. Borges had the following information—she had three prior patients who suffered permanent hair loss after taking Taxotere, and she read numerous articles in dermatology publications, as well as an article by Dr. Scot Sedlacek describing the risk of permanent alopecia associated with Taxotere. Defendants' Motion reveals that this information was shared with Dr. Gahan. Despite this knowledge, Dr. Gahan chose to proceed with a Taxotere-containing regimen as recommended and ultimately prescribed by Dr. Gahan.

As Defendants note, Dr. Borges presented Plaintiff Gahan with two chemotherapy options—a Taxotere-containing regimen and a non-Taxotere-containing regimen. Dr. Borges testified that while the Taxotere regimen was her “preferred regimen,” the two regimens “were considered equivalent by the field.”¹⁴ Dr. Borges and Plaintiff discussed many times the pros and cons of these two regimens, weighing Plaintiff’s concerns about permanent hair loss against other concerns.

While Dr. Borges recommended the Taxotere-containing regimen, the evidence supports the inference that she would have prescribed Gahan a non-Taxotere regimen if Gahan had preferred that. Indeed, Dr. Borges testified that she merely guides her patients to their decisions:

[T]here's a lot of conversations in my world that are teaching someone to understand risk assessment, benefit assessment, and weigh those for themselves, and put it in their view of the world and their personal health and their choice and their willing[ness] to

¹⁴ Doc. 8062-3 at 14.

accept diminishment of the quality of life in a temporary way and some permanent risks that can occur with these treatments that we're recommending. And then help guide her to the best-informed choice that she can make for herself.¹⁵

Regarding Gahan specifically, Dr. Borges testified as follows:

Kelly had asked a lot of different questions about the pros and cons of both regimens and a lot of questions about what I had seen women experience with the cold caps. When I had asked her to give me a decision because her starting date that she had selected was coming up, it is my recollection that she chose the TCH regimen, and she did that after fully evaluating all of her choices.

The evidence shows then that Dr. Borges made her prescribing decision only after several robust discussions with Dr. Gahan about her two options. It was Dr. Gahan who made the ultimate decision to proceed with the Taxotere regimen, and she did so after conducting her own research in addition to her conversations with Dr. Borges. Dr. Gahan visited the "Taxotears" website and read posts from women discussing their hair loss.¹⁶ Dr. Gahan also searched medical search engines and found two articles describing a link between Taxotere and permanent hair loss.¹⁷

Defendants also emphasize that Dr. Borges had independent knowledge of the risk of permanent hair loss associated with Taxotere, yet she recommended Taxotere to Dr. Gahan anyway. As previously noted, Dr. Borges testified that before she treated Gahan, she had three patients who had used a Taxotere regimen and then suffered permanent hair loss. This information

¹⁵ Doc. 8062-3 at 12–13.

¹⁶ Doc. 5730-7 (pp. 22–25).

¹⁷ *Id.* The Court notes that Dr. Borges advised Dr. Gahan to be wary of some of this information because it may be unreliable. Nonetheless, Dr. Gahan had knowledge of it.

was shared and discussed with Dr. Gahan. Dr. Borges also provided Dr. Gahan with the Sedlacek article discussing the risk of permanent alopecia associated with Taxotere. Unsurprisingly, in her testimony, Dr. Borges testified that she still would have recommended Taxotere even if there had been a warning about permanent hair loss in the label.¹⁸ She testified as follows:

Q: And no matter what the label change that might have happened for the Taxotere label would not have changed your recommendation [of a Taxotere-containing regimen]?

A: Not for the use of the chemotherapy regimen. I do think it might have swayed [Gahan's] decision to use the cold caps had I been able to give her real information as opposed to three anecdotal cases.¹⁹

Based on Dr. Borges's testimony, a label change would not have changed her decision to recommend Taxotere. Further, Dr. Borges believes that a label change would not have affected Dr. Gahan's decision to use the Taxotere regimen as recommended by Dr. Borges. She believes it may, however, have swayed Dr. Gahan to use cold caps with the Taxotere regimen.

The Court notes that Dr. Gahan made an informed choice not to use the cold caps, despite Dr. Borges's recommendation. Dr. Gahan was aware of reports of permanent hair loss associated with Taxotere, and she discussed this at length with Dr. Borges. She chose not to proceed with cold caps because of her fear of cell migration. One of her medical providers wrote that Dr. Gahan "decided the process of hair preservation was not worth the risk of leaving circulating tumor cells in her body."²⁰ At her deposition, Dr. Gahan testified that she was willing to lose her hair for four months to eliminate any possibility

¹⁸ Doc. 8062-1 at 6.

¹⁹ Doc. 8062-1 at 6.

²⁰ Doc. 5370-7 (p. 250).

of circulating tumor cells.²¹ The Court notes that cold caps were in the infancy stage of use at the time of Dr. Gahan's treatment. Despite her decision not to use cold caps, Dr. Gahan chose to proceed with Taxotere.

This Court cannot escape the undeniable conclusion that Dr. Gahan was aware of the risk of permanent hair loss and nonetheless proceeded with the Taxotere chemotherapy regimen. The Court finds that Plaintiff has failed to create an issue of fact on whether Dr. Borges's prescribing decision would have changed if Sanofi had adequately warned of the alleged risk of permanent alopecia associated with Taxotere. Accordingly, because Plaintiff cannot create an issue of fact on causation, Defendants' Motion is granted on Plaintiff's claims for negligence and failure to warn.

II. Plaintiff's Fraud-Based Claims

Defendants argue that they are entitled to summary judgment on Plaintiff's remaining claims of fraudulent misrepresentation, fraudulent concealment, and fraud and deceit. Defendants aver that for these causes of action, a plaintiff must show reliance on a misrepresentation. Defendants argue that Dr. Gahan cannot make such a showing because Defendants never made any representations directly to Plaintiff. Defendants argue that pursuant to the learned intermediary doctrine, they had no duty to communicate directly with Plaintiff. Defendants further aver that because no representation was made directly to Gahan, Gahan cannot show that she relied on such a representation.

In Colorado, to establish fraud, a plaintiff must present evidence that (1) the defendant made a false representation of a material fact, knowing that

²¹ *Id.*

representation to be false; (2) that the person to whom the representation was made was ignorant of the falsity; (3) that the representation was made with the intention that it be acted upon; and, (4) that the reliance resulted in damage to the plaintiff.²² Plaintiff Gahan cannot show that she relied on a misrepresentation by Defendants. As discussed herein, Dr. Gahan had knowledge of the risk of permanent alopecia associated with Taxotere yet chose to take a Taxotere regimen anyway. She did not rely on Defendants' allegedly inadequate warning label. The evidence shows that regardless of the adequacy of Defendants' warning, Plaintiff would have taken a Taxotere regimen. Accordingly, because Plaintiff cannot create an issue of fact on the reliance element, summary judgment is granted on her fraud-based claims.

CONCLUSION

For the foregoing reasons, **IT IS ORDERED** that Defendants' Motion for Summary Judgment (Doc. 5730) is **GRANTED**. Plaintiff's claims are **DISMISSED WITH PREJUDICE**.

New Orleans, Louisiana this 26th day of February, 2020.



JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE

²² Coors v. Security Life of Denver Ins. Co., 112 P.3d 59, 66 (Colo. 2005). *See also* NetQuote, Inc. v. Byrd, 2008 WL 2552871, at *3 (D. Colo. June 17, 2008); BP Am. Prod. Co. v. Patterson, 263 P.3d 103, 109 (Colo. 2011) (setting forth elements of fraudulent concealment and discussing reliance element).